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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,128	01/02/2002	Fang Liao	11245/46902	8763

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KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/040,128	LIAO ET AL.	
	Examin r	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this c mmunicati n appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-22 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 10-12, as specifically drawn to an antibody that binds to a site on a VE-cadherin, said site being within the about 15 N-terminal amino acids of domain 1 of a VE-cadherin including insertions, deletions or substitutions of from 1 to about 5 amino acids relative to a native VE-cadherin amino acid sequence, and pharmaceutical composition thereof, classified in class 530, subclass 387.1.

II. Claims 1-7, 10-12, as specifically drawn to an antibody that binds to a peptide having an amino acid sequence of SEQ ID NO:1 and pharmaceutical composition thereof, classified in class 530, subclass 387.9.

III. Claims 1-7, 10-12, as specifically drawn to an antibody that binds to a peptide having an amino acid sequence of SEQ ID NO:2 and pharmaceutical composition thereof, classified in class 530, subclass 387.9.

IV. Claims 1-7, 10-12, as specifically drawn to an antibody that binds to a peptide having an amino acid sequence of SEQ ID NO:3 and pharmaceutical composition thereof, classified in class 530, subclass 387.9.

V. Claims 8-9, as specifically drawn to ONE hybridoma which produces ONE monoclonal antibody from those listed in Groups I-IV above, classified in class 435, subclass 326.

Upon election of Group V, applicant should indicate the antibody of choice from Groups I-IV above as each antibody represents and independent and or distinct product.

VI. Claims 13-19, drawn to methods of inhibiting angiogenesis in a mammal wherein the condition of said mammal **is solely associated with a neoplastic condition** comprising administering ONE of the pharmaceutical compositions from Groups I-IV above, classified in class 424, subclass 139.1.

Upon election of Group VI, applicant should indicate the antibody of choice from Groups I-IV above as each antibody represents and independent and or distinct product. Further note, this does not include search and examination of those conditions which are NOT associated with a neoplastic condition, i.e. collagenous vascular disease, rheumatoid arthritis.

VII. Claims 13-14 drawn to methods of inhibiting angiogenesis in a mammal wherein the condition of said mammal **is solely associated with an ophthalmologic condition including retrolental fibroplasias, diabetic retinopathy, and neovascular glaucoma,** comprising administering ONE of the pharmaceutical compositions from Groups I-IV above, classified in class 424, subclass 139.1.

Upon election of Group VII, applicant should indicate the antibody of choice from Groups I-IV above as each antibody represents and independent and or distinct product. Further note, election of this group does not include search and examination of those conditions that are NOT associated with an ophthalmologic condition.

VIII. Claims 13-14, 17-18 drawn to methods of inhibiting angiogenesis in a mammal wherein the condition of said mammal **is solely associated with an autoimmune disorder, collagenous vascular disease, rheumatoid arthritis, fibrotic disorders, and age-related muscular degeneration** comprising administering ONE of the pharmaceutical compositions from Groups I-IV above, classified in class 424, subclass 139.1.

Upon election of Group VIII, applicant should indicate the antibody of choice from Groups I-IV above as each antibody represents and independent and or distinct product. Further note, this does not include search and examination of those conditions that are NOT associated with autoimmune disorders.

IX. Claims 20-21, as specifically drawn to ONE nucleic acid (and associated vector) which encodes a coding sequence for ONE of the antibodies from those listed in Groups I-IV above, classified in class 536, subclass 23.53.

Upon election of Group IX, applicant should indicate the antibody of choice from Groups I-IV above as each antibody represents and independent and or distinct product.

X. Claim 22, drawn to a method of gene therapy comprising administering ONE of the nucleic acids of Group IX above in a mammal to inhibit angiogenesis at a predetermined site or tumor neovascularization, classified in class 514, subclass 44.

Upon election of Group X, applicant should indicate the nucleic acid of choice which encodes ONE of the antibodies from Groups I-IV above as each antibody represents and independent and or distinct product.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-V and IX represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. For example, the antibodies listed in Groups I-IV are distinct products in that they are specific for distinctly different peptides which comprise different amino acid sequences wherein the binding regions of said antibodies would further comprise distinctly different variable and or hypervariable regions. Furthermore, the burden of searching different amino acid sequences is high because of the large number of data bases which must be searched. Currently, there are nearly 7 different databases comprising

different amino acid sequences which the Office must include when searching different sequence identifers. This further extrapolates to the burden of searching distinctly different nucleic acid sequences which encode the antibodies and the large number of hybridomas which produce said antibodies.

The inventions of Groups VI-VIII, and X are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. For example, methods of inhibiting neoplastic conditions have distinctly different response variables and criteria for success for those methods which are drawn to conditions associated with eye disorders and autoimmune disorders. As such, it would require different searches and considerations in the literature.

The invention of Groups I-V and the method of Groups VI-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a variety of materially different processes such as affinity chromatography, methods of treating cancer, or methods of treating cell proliferative conditions including rheumatoid arthritis.

The invention of Groups IX and the method of Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid product as claimed can be used in a materially different process such as affinity chromatography, or methods of gene therapy to treat age-related muscular degeneration.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Note:

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of

35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
November 6, 2003